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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,833	08/03/2001	Yoshikatsu Ueda	H-988	7520

7590 12/17/2003

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EXAMINER	
CLOW, LORI A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/920,833	UEDA ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *5-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election without traverse of Group I, claims 1-4 in the paper filed 17 October 2003 is acknowledged.

Priority

Applicant's claim to foreign priority document JP 2000-250533 is denied. No English translation has been filed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

Quantity of Experimentation and Nature of the Invention

a) and d) In order to practice the claimed invention one of skill in the art must be able to make or use a chip which contains genetic information necessary for prescribing a genomic drug. For the reasons discussed below, this constitutes undue experimentation.

Guidance and Nature of the Invention

b) and c) The specification provides no direction or working examples on how to acquire genetic information necessary for prescribing a genomic drug. Further, there is no information available in the specification about what genetic information is being disposed on the chip. Is it all genetic information from an individual allele or chromosomal genetic information from an individual or a whole population? Probes are selectively disposed on a chip, but how are they disposed selectively? The specification does not address this process. The claims require that necessary genetic information be acquired. What is necessary information? How does one obtain necessary information? Furthermore, what is the genomic drug? Is it a drug specific to an individual or a set of individuals with similar mutations? It is not explained how this drug is obtained or where it comes from.

Further, the specification is devoid of information on exactly how the existence or nonexistence of a drug to be prohibited from being taken is ascertained. Is this chip somehow tied to a database that contains such information, such as the Physician's Desk Reference? Without guidance on the specific steps to generate this genetic chip, the present invention is not enabled.

The State of the Prior Art

e) and g) It would have been well known in the art that the study of the association between genetics and drug response is a leading area. The move toward personalized medicine has been well documented (see for example Wolf et al. BJM (2000) 8 April, Vol. 320, pages 987- 990 and Roses. Nature (2000) 15 June, Vol. 405, pages 857-865). In fact it has been suggested that prescription guidelines be established and prescribing advice given based upon related genotype with possible drug interactions. However, as stated by Roses this is a complicated scenario. Every individual is a product of the interaction of their genes with the environment and the ability to use genetic profiles for patients will potentially provide information on the efficacy and safety of a drug for that individual. There are several problems that need to be resolved to implement this type of medicine, one of which is target selection. How do we deal with the limited number of molecular target families that have been identified and which ones are better than others? There are many other issues like these to be addressed and without detailed experimentation and descriptions in the instant specification, one of skill in the art would not know begin to know what genetic information to dispose on a chip or what is necessary or what specific information is needed in order to make the right prescription. For these reasons, it would require undue experimentation to make or use a chip as claimed.

The Relative Skill in the Art

f) The skill of those in the art of pharmacogenomics is high.

The Breadth of the Claims

h) The claims are broad because they are drawn to a chip that comprises probes for acquiring genetic information without identifying the probes or stating **what** genetic information

or genomic drug is to be acquired/recognized. The skilled practitioner would first turn to the instant specification for guidance to practice methods of ascertaining what genetic information to include on the chip or how to prescribe based upon that information. However, the instant specification does not provide specific guidance to practice these embodiments. As such, the skilled practitioner would turn to the prior art for such guidance, however, the prior art shows that such predictions require substantial additional work and research. Finally, said practitioner would turn to trial and error experimentation to determine whether said sequences are indeed similar through the methods discussed by Wolf et al. and Roses, including substantial bench research. Such represents undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims require that necessary genetic information be acquired. What is necessary information? Is it information that pertains to only a specific disease or disorder?

The claims also require that probes are selectively disposed on a chip, but how are they disposed selectively? It is unclear what the metes and bounds of "selective" is in this context.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

While the instant invention is not enabled for the reasons stated above, prior art does apply due to the broad nature of the claims. In the instant application the claims are directed to a chip comprising probes. As set forth in MPEP 2111.02, where an intended use does not structurally limit a product claim, the intended use is not given patentable weight.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,174,683 B1 (Hahn et al.).

Hahn et al. teach an improved biochip with biomolecular probes bound thereto (see summary of invention, column 4), thus anticipating the chips with probes disposed thereon of claims 1-4.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,171,793 B1 (Phillips et al.)

Phillips et al. teach a gene probe array including a variety of genetic probes having different receptors (see abstract), thus anticipating the chips with probes disposed thereon of claims 1-4.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,489,159 B1 (Chenchik et al.),

Chenchik et al. teach arrays of a plurality of different heterogeneous polymeric target compositions immobilized on the surface of a solid support. The targets are generally biopolymeric compounds such as nucleic acids (see abstract), thus anticipating the chips with probes disposed thereon of claims 1-4

No claim is allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

MARJORIE MORAN
PATENT EXAMINER
Marjorie A. Moran

December 13, 2003

Lori A. Clow, Ph.D.
Art Unit 1631
Lori A Clow